

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor: Harder et al.

Examiner: Melanie Ruano Tyson

Ser. No.: 10/706,717

Art Group: 3773

Title: Endoprosthesis

Filed: 11 November 2004

Date: 7 May 2008

**PRE-APPEAL BRIEF REQUEST FOR REVIEW AND
STATEMENT ACCOMPANYING REQUEST FOR PRE-APPEAL BRIEF REVIEW**

A pre-appeal brief request for review is hereby made. The Applicants maintain that the Examiner has not established *prima facie* cases of obviousness of pending claims. The Examiner rejected the pending claims 1–17 and 19–35 under 35 U.S.C. § 103(a) as being obvious over U.S. Pat. No. 6,979,347 to Wu (hereinafter “Wu”). Claims 18 and 36–37 stand rejected under 35 U.S.C. § 103(a) as being obvious over Wu in view of U.S. Patent No. 6,676,697 to Richter (hereinafter “Richter”).

Under *Graham v. John Deere Co.*, an obviousness determination under 35 U.S.C. 103 requires analysis of 4 factors:

- (A) Determining the scope and contents of the prior art;
- (B) Ascertaining the differences between the prior art and the claims in issue;
- (C) Resolving the level of ordinary skill in the pertinent art; and
- (D) Evaluating evidence of secondary considerations.

Additionally, when applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

- (A) The claimed invention must be considered as a whole;
- (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
- (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

(MPEP § 2141, *quoting Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).)

Scope and Content of Prior Art

Wu makes no mention of the use of any specific magnesium alloy, although Wu does generally disclose the option of using a magnesium-based alloy in a stent. Wu merely mentions magnesium once in passing among a list of potential components, “Arm elements 22 and connecting elements 24 are typically fabricated from a metallic material or an alloy, such as stainless steel (e.g., 316L), MP35N, MP20N, tantalum, nickel-titanium alloy (commercially available as Nitinol TM), platinum-iridium alloy, gold, magnesium, or combinations of alloys.” (Column 4, lines 30-35).

The Examiner cites U.S. Pat. No 4,401,621 to Unsworth (hereinafter “Unsworth”) as showing that magnesium alloys such as those claimed, are known in the art. However, the Examiner has not relied on Unsworth in combination with Wu, but merely cites Unsworth as an example showing that such magnesium alloys are known in the art. However, Unsworth does not teach or suggest that such alloys may be useful in stents or even in medical implants in general. Instead, Unsworth provides such alloys as being useful in aerospace applications (col. 1, lines 6-12) and accordingly tests the properties of the disclosed alloy at temperatures 200 °C and above, which are far outside the range of physiological temperature, 37 °C.

Richter provides no teaching or suggestion of the use of a magnesium alloy in an endoprosthesis. The Examiner only relies on Richter for the teaching of “a stent having a plurality of members and connectors” in which reducing the width of the connectors provides a device with greater flexibility.” (Office Action of Feb 7, 2008, page 3, lines 20-22).

Level of Ordinary Skill in the Art

While the Examiner has not provided any specific finding regarding the level of ordinary skill in the art, the Applicants maintain that one of ordinary skill in the art would hold an undergraduate degree in Biology, Biomedical Engineering or a similar, closely related area.

Differences between the Prior Art and the Claims in Issue

The difference between Wu and claim 1 is the difference between a bare recitation of any magnesium alloy and a specific magnesium alloy containing > 90 percent magnesium, 3.7 - 5.5 percent yttrium, 1.5% - 4.4% rare earths and <1 percent other elements. Wu provides no teachings or suggestions regarding use of a composition containing other components of the claimed invention, such as yttrium, in an endoprosthesis. Therefore, Wu is non-enabling for the use of the claimed composition in an endoprosthesis. Additionally, as provided above, Richter provides no teaching or suggestion of any magnesium alloy, much less the claimed magnesium alloy.

Argument

While previous decisions have held that a composition is obvious if it contains components in amount ranges that overlap with previously disclosed ranges, this rejection is distinguishable from such decisions. Wu does not disclose a composition containing a range of amounts for each component of a magnesium alloy. Rather, Wu only mentions magnesium and magnesium alloys in general. Under the Examiner's reasoning, a virtually limitless number of alloys are encompassed by, and therefore anticipated by, Wu's disclosure of magnesium alloys in general.

The Examiner also states that it would have been obvious to utilize a "well known alloy" as provided by Unsworth, in Wu's stent. To support this contention, the Examiner states, "it has been held to be within the general skill of a worker in the art to select a known material on the basis of suitability for the intended use as a matter of design choice." However, it is clear that the Examiner is using hindsight, provided by the claimed invention, to find that Unsworth's alloy is "suitable for the intended use" in a stent. As stated previously, neither Wu nor Unsworth teach or suggest that the claimed magnesium alloy composition would even be suitable for use in an endoprosthesis. Neither Wu nor Unsworth nor Richter teach or suggest that such a material is biocompatible generally. They also do not suggest the biocompatibility of any composition even remotely related to the claimed composition.

The Examiner also provides no teaching or suggestion, either in the cited prior art or in the knowledge generally available to one of ordinary skill in the art, that yttrium is compatible with use in an endoprosthesis. It is likewise neither taught nor suggested in the prior art that the

use of such an alloy would provide advantageous properties such as prevention of restenosis from sustained tissue growth prevention, a lack of inflammatory effect, and decomposition products which not only have no negative effect, but can actually have a positive effect, as provided by the claimed invention (see paragraphs 0006 and 0009). Additionally, while the Examiner at least theoretically does not rely on Unsworth, and Unsworth indicates that the a magnesium alloy provides good tensile properties, there is no indication that such an alloy would have other properties also required in an endoprosthesis such as torsional strength, minimization of re-stenosis, or minimization of inflammation. Contrary to the Examiner's assertions, these properties do not "logically flow from the teaching of the prior art" where the prior art only shows the usefulness of the prior composition in aerospace applications. General suitability for "engineering applications" does not equate to biocompatibility, much less the unexpected advantageous properties listed above.

Therefore considering the claimed invention and the cited references as a whole, there would be no suggestion to one of ordinary skill in the art to arrive at the claimed invention based on Wu, alone or in combination with Unsworth. Withdrawal of the rejection of claims 1-17 and 19-35 under 35 U.S.C. § 103(a) in view of Wu is respectfully requested. Likewise, neither Wu nor Richter teach or suggest all of the claim limitations of claims 18, 36 and 37, which indirectly depend from claim 1. These claims also patentably distinguish over the cited prior art. Withdrawal of the rejection of claims 18, 36 and 37 under 35 U.S.C. § 103(a) as obvious over Wu in view of Richter is also respectfully requested.

The Applicants maintain that the pending claims patentably distinguish over the cited prior art and request reversal of the Examiner's final rejection of claims 1-37. The issuance of a Notice of Allowance is respectfully requested.

The outstanding Office Action was mailed on February 7, 2008. The Examiner set a shortened statutory period for reply of 3 months from the mailing date. No extension of time is believed to be required with the filing of this paper. However, in the event that the need for a petition for an extension of time has been overlooked, a conditional petition for the necessary extension of time is hereby made with this Notice of Appeal and Request for Pre-appeal Brief Review. The Commissioner is authorized to charge any fee required with the filing of this response or to credit any overpayment to Deposit Account 15-0450.

Respectfully submitted,

/John J. Cunniff/

John J. Cunniff
Reg. No 42,451
Hahn Loeser + Parks LLP
One GOJO Plaza
Suite 300
Akron, OH 44311

Attorney for Applicants